

VIDA LED Surgical Lighting System, V series

510(K) Summary

1. Type of Submission: Traditional

2. Preparation Date: April 3, 2014

3. Revised Date: N/A

4. <u>Submitter:</u> ConVida Healthcare & Systems Corporation

Address: No.33, Dinghu Rd., Guishan Township, Taoyuan

County 33378, Taiwan

Phone: +886-3-318-3777 #332

Fax: +886-3-318-7799

Contact: Sharon Lee / Regulatory Engineer

Registration Number: 3010402711

5. Identification of the Device:

Proprietary/Trade name: VIDA LED Surgical Lighting System, V series

Common Name: Surgical lamp

Classification Name: Light, Surgical, Ceiling Mounted

Device Classification: 2

Regulation Number: 878.4580

Panel: General & Plastic Surgery

Product Code: FSY

6. Identification of the Predicate Device:

Predicate Device Name: VIDA LED Surgical Lighting System-X series

Manufacturer: ConVida Healthcare & Systems Corporation

Product Code: FSY

510(K) Number: K132307



VIDA LED Surgical Lighting System, V series

7. Intended Use and Indications for Use of the Subject Device:

Intended Use:

The VIDA LED Surgical Lighting System, V series provide illumination for surgery or examination at operating room.

Indications for Use:

The VIDA LED Surgical Lighting System, V series provide illumination for surgery or examination at operating room.

8. Device Description:

The VIDA LED Surgical Lighting System, V series provide illumination for surgery or examination at operating room.

VIDA LED Surgical Lighting System, V series uses high-efficacy light-emitting-diodes (LED) as light source which provides high brightness and no extra heat; the design of the optical mechanism gives a characteristic of less shadow which is significant to the surgeon during the operation. Given of its modular design, VIDA V provided many options for configurations and can be installed in an operating room with or without a laminar air flow system.

The features of VIDA LED Surgical Lighting System, V series are as followed:

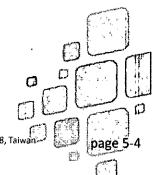
- Prism-Based Light Delivery Technology: ConVida's patented optical system, that
 combines an advanced refractive prism lens and innovative high-power LED technology,
 focuses light into an intense 110cm (43") focal cylinder, eliminating the need for
 refocusing when adjusting surgical table.
- Consistent Illumination at Different Color Temperature Settings: VIDA V series
 lighthead's color temperature can be individually adjusted at any of the 5 settings (3500K, 4000K, 4250K, 4500K, 5000K) with a high CRI of 95, R9 94.
- Optimal Brightness without Glare: Elegant, sophisticated optical system consists up to 2 types of high-power LEDs and multiple refractive prisms produces up to 160,000 lux of intensity without discomfort flare/glare.
- VIDA V light gives the Surgeon Control: On the VIDA V, both lighthead focus and light
 intensity can easily be adjusted via turning the lighthead handle. They are also adjustable
 from the standard lighthead control or optional VIDA V Control Center on the wall.
- Long Lifetime: Under normal use, VIDA V LEDs enjoy an extremely long lifetime of 50,000+ hours (70% lumen maintenance at 50,000 hours).
- Two Types of Ambient Lights (Option): 5% central luminance (GUIDE lighting mode) can be configured through standard lighthead control. Guide lighting mode may be used as ambient lighting for manipulating endoscopy instruments or lighting diagnostic.



VIDA LED Surgical Lighting System, V series

and is controllable on the optional VIDA V Control Center.

- Camera-Ready Lighthead is Built into the System: All VIDA V lightheads are pre-wired
 with HD cabling for taking an optional HD 1080p Camera Handle. The HD 1080p Camera
 Handle is removable from one VIDA V lighthead to another providing superb flexibility
 for recording.
- Exceptional Maneuvering Flexibility: The exceptionally durable non-sterile handles allow
 easy positioning of all our lightheads. Each lighthead rotates a full 360°so that the system
 can be quickly and easily positioned for any surgical procedure. Individual lightheads can
 be lower to 810mm above the floor providing excellent low lateral illumination.
- Sleek Non-Sterile Handle: The lighthead has is molded with a sleek all-around handle that facilitates easy repositioning and adds modern elegance to O.R. setting
- Easy-to-clean Compact Lighthead: Made of tough molded materials, the VIDA V series lightheads are completely sealed which helps prevent biocontaminants from entering the operative site and lighthead itself, and facilitates cleaning.
- HD Supported Suspensions: All VIDA V suspensions are prewired with video cables to
 deliver information users need within and without the surgical field. Images are in crisp
 and accurate HD format with no signal conversion necessary and no loss of video quality.
- Heavy Duty HD Flat Monitor Suspension: Flat Monitor Suspension Arms support single/dual monitors up to a total of 24 kg (53 lbs), making them ideal for surgical displays up to 32". Large display compatibility allows the surgical team to see more of the procedural area. Optional Medical Grade LCD Displays from SONY also offer uncompressed HD video at 1080p which shows true images from SD- and HD-endoscopes, ultrasound, C-arms and other equipment.
- Optimal HD Connectivity: The built-in fiber optic cable allows the suspension to support monitors featuring Full HD 1920 x 1080 video signals.
- Low Profile Suspension: Low-profile cardinal lighthead suspension is offered for rooms with ceiling lower than 280mm.
- Failsafe Design: The unit is protected against an electrical power failure, thus ensuring that all surgical procedures can continue without interruption.





VIDA LED Surgical Lighting System, V series

9. Performance Summary:

This device conforms to the standards listed as below:

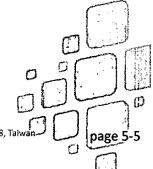
- IEC 60601-1:2005 Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-2-41:2009 Medical Electrical Equipment Part 2-41: Particular requirements for the basic and essential performance of surgical luminaires and luminaires for diagnosis
- IEC 60601-1-2:2007 Medical Electrical Equipment, Part 1-2: General requirements for basic Safety and essential performance Collateral Standard: Electromagnetic Compatibility Requirements and tests
- IEC 62304:2006 Medical Device Software: Software Life Cycle Process
- ISO 14971:2007 Medical Device: Application of Risk Management to Medical Devices
- ISO 15223-1:2012 Medical Device: Symbols to be used with medical device labels, labeling and information to be supplied, part 1: General requirements
- ISO 17664:2004 Sterilization of medical devices: information to be provided by the manufacturer for the processing of resterilizable medical devices

10. Safety and Effectiveness

The bench testing result shows that the proposed device is complied with IEC standards, and as safe as the predicate device.

11. Substantial Equivalence Determination:

The VIDA LED Surgical Lighting System, V series is substantially equivalent to VIDA LED Surgical System-X series. There are no negative effect on safety or effectiveness between VIDA LED Surgical Lighting System, V series and the predicate device. The following is the detail of the compared item.





VIDA LED Surgical Lighting System, V series

	Propose	d Device	Predicat	e Device
Item	The VIDA LED Surgical Lighting System, V series		The VIDA LED Surgical Lighting	
			System-X series	
Manufacturer	ConVida Healthcare & Systems		ConVida Healthcare &	
	Corp.		Systems Corp.	
Classification	Class II		Class II	
Regulation Number	878.4580		878.4580	
Product Code	FSY		FSY	
Intended Use	The VIDA LED Surgical Lighting		VIDA LED Surgical Lighting	
	System, V series provide		System- X series provide	
	illumination for surgery or examination at operating		illumination for surgery or	
			examination at operating	
	room.		room.	
Lighthead model	V70	V50	X70	X50
Similarity				
Over-the-counter Medical	No		No	
Device			<u> </u> 	
Light Source	LED	LED	LED	LED
Color Rendering Index	95	95	95	95
(CRI)		•		
LED Life time (hrs)	50,000	50,000	50,000	50,000
Difference	, e.			* N :
Diameter of Light Head	82	72	72	58
(cm)				
Number of LEDs	55	44	90	60
Central illumination (at	160,000	140,000	160,000	130,000
1m) (lux)				
Color temperature,	3500-5000K	3500-5000K	4200	4200
Kelvins	(3500K,	(3500K,		
	4000K,	4000K,		
	4250K,	4250K,		
	4500K,	4500K,		
	5000K)	5000K)		
Total irradiance (W/m²)	592	518	< 656	<u></u> <533
Irradiance intensity	3.7	3.7	4.1	D (4.1.
(mW/m²lux)				



VIDA LED Surgical Lighting System, V series

d ₅₀ /d ₁₀ (%)	56	59	> 50	> 50
Light field size, d ₁₀ (cm)	17~30	16~27	20~32	18~28
Depth of illumination	20%: 110	20%: 100	20%: 140	20%: 145
L1+L2 (cm)	60%: 45	60%: 45	60%: 71	60%: 82
Power Consumption	100W@24Vdc	100@24Vdc	100W	80W

12. Non-clinical Performance Testing:

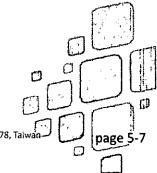
Performance testing were conducted to verify that the VIDA LED Surgical Lighting System, V series meets the requirements for Medical Electrical Equipment as defined in IEC 60601-1, IEC60601-2-41, and IEC 60601-1-2

13. Clinical Performance Testing:

No Clinical testing is required for this device classification submission.

14. Conclusion:

The VIDA LED Surgical Lighting System, V series submitted in this 510(K) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared VIDA LED Surgical Lighting System-X series which is the subject of K132307. Differences between the devices cited in this section do not raise any new issue of safety or effectiveness. After analyzing bench test, safety testing data, it can be concluded that VIDA LED Surgical Lighting System, V series is substantially equivalent to the predicate device.





Food and Drug Administration 10903 New Hampshire Avenue Document Control Center - WO66-G609 Silver Spring, MD 20993-0002

June 9, 2014

ConVida Healthcare & Systems Corporation Sharon Lee, Regulatory Engineer No. 33, Dinghu Road Guishan Township, Taoyuan County 33378, Taiwan

Re: K140930

Trade/Device Name: VIDA LED Surgical Lighting System, V Series

Regulation Number: 21 CFR 878.4580 Regulatory Name: Surgical lamp

Regulatory Name. Surgical lamp

Regulatory Class: Class II

Product Code: FSY Dated: April 09, 2014 Received: April 11, 2014

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

cc: DMC 510(k) Staff Division D.O.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

i10(k) Number <i>(if known)</i> (140930	
Device Name VIDA LED Surgical Lighting System, V series	
ndications for Use (Describe) The VIDA LED Surgical Lighting System, V series provide illu	umination for surgery or examination at operating room.
Type of Use (Select one or both, as applicable)	
Prescription Use (Part 21 CFR 801 Subpart D)	Over-The-Counter Use (21 CFR 801 Subpart C)
PLEASE DO NOT WRITE BELOW THIS LINE - CO	ONTINUE ON A SEPARATE PAGE IF NEEDED.
FOR FDA U	
Neil R Ogden -S 2014.06.05 15:06:29 -04 00	
ZU 17.00.00 10.00.20 -07.00.20	ld tourished

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."